## A Phase III multicentre randomised clinical trial of R-CHOP14 vs R-CHOP21 in newly diagnosed diffuse large B-cell lymphoma

| | | | | |
|---|---|---|---|---|
| Patient initials | | | Date of birth | (dd/mm/yyyy) |
| Centre | | | Consultant | |
| Sex | | 1=M, 2=F | NHS Number | |

**To randomize a patient please fax completed form to 0207 679 9861.** For queries please call The Lymphoma Trials Office 0207 679 9860.

# Registration form (page 1 of 6)

**Eligibility checklist**

| | **Inclusion criteria** | **Yes** | **No** |
|---|---|---|---|
| 1 | Age ≥18 years | | |
| 2 | Histologically proven diffuse large B-cell lymphoma, anti CD20 positive | | |
| 3 | No previous chemotherapy, radiotherapy or other investigational drug for this indication | | |
| 4 | Bulky stage IA (defined as lymph node or lymph node mass greater than 10cm in diameter), IB, stage II, stage III and IV | | |
| 5 | WHO performance status 0-2 | | |
| 6 | Adequate bone marrow function with platelets $>100x10^9$/l; neutrophils $>1.5x10^9$/l at the time of study entry unless attributed to bone marrow infiltration by lymphoma | | |
| 7 | Serum creatinine <150μmol/l, serum bilirubin <35μmol/l and transaminases <2.5upper limit of institutional normal range unless attributed to lymphoma | | |
| 8 | Normal MUGA or echocardiogram without any areas of abnormal contractility and acceptable left ventricular ejection fraction (LVEF) ≥50% (only applicable if aged over 70, known diabetic over 65, past history of cardiac disease or hypertension or abnormal resting ECG) | | |
| 9 | No concurrent uncontrolled medical condition | | |
| 10 | No active malignant disease other than basal or squamous cell carcinoma of the skin or carcinoma in situ of the uterine cervix in the last 10 years | | |
| 11 | Life expectancy >3 months | | |
| 12 | Adequate contraceptive precautions for all patients of child bearing potential | | |
| 13 | Written, informed consent | | |

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# Registration form (page 2 of 6)

**Eligibility checklist**

| | **Exclusion criteria** | **Yes** | **No** |
|---|---|---|---|
| 1 | T-cell lymphoma or transformed follicular lymphoma | | |
| 2 | Previous history of treated or non-treated indolent lymphoma. However patients not previously diagnosed who have a diffuse large B-cell lymphoma with some small cell infiltration in bone marrow or lymph node may be included | | |
| 3 | Past history of heart failure or uncontrolled angina pectoris | | |
| 4 | Central nervous system, meningeal involvement or cord compression by the lymphoma | | |
| 5 | Cardiac contra-indication to doxorubicin (abnormal contractility on echocardiography or nuclear medicine examination (MUGA)) | | |
| 6 | Neurological contra-indication to vincristine (e.g. pre-existing diabetic neuropathy) | | |
| 7 | Any other serious active disease | | |
| 8 | General status that does not allow the administration of 8 courses of CHOP according to the investigator | | |
| 9 | Positive serology for HIV, Hepatitis B or Hepatitis C | | |
| 10 | Medical or psychiatric conditions that compromise the patients ability to give informed consent | | |

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# Registration form (page 3 of 6)

**Pre-treatment assessment**

| **Date of assessment** | | (dd/mm/yyyy) |
|---|---|---|
| Height | | (cms) |
| Weight | | (kgs) |
| WHO performance status | | 0-2 |
| B Symptoms | | 1=Absent, 2=Present |

| | | |
|---|---|---|
| Date of diagnostic biopsy | | (dd/mm/yyyy) |
| Stage | | 1= IA, 2=IB 3=II, 4=III, 5=IV |
| Bulky disease | | 1=Absent, 2=Present |

**Haematology**

| **Date of haematology** | | (dd/mm/yyyy) |
|---|---|---|
| | **Value** | **Units** |
| Haemoglobin | | g/dl |
| Platelets | | $x10^9$/l |
| White blood cells | | $x10^9$/l |
| Neutrophils | | $x10^9$/l |
| Lymphocytes | | $x10^9$/l |

**Biochemistry**

| **Date of biochemistry** | | (dd/mm/yyyy) | |
|---|---|---|---|
| | **Value** | **Units** | |
| Sodium | | mmol/l | |
| Potassium | | mmol/l | |
| Creatinine | | μmol/l | |
| Urea | | mmol/l | |
| Albumin | | g/l | |
| Total protein | | g/l | |
| Calcium | | mmol/l | |
| Phosphate | | mmol/l | **Normal ranges** |
| LDH | | IU/l | |
| Bilirubin | | μmol/l | |
| Alkaline phosphatase | | IU/l | |
| AST | | IU/l | |
| ALT | | IU/l | |
| β2 microglobulin | | mg/l | |

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# Registration form (page 4 of 6)

## Pre-treatment assessment

| **Investigation** | **Date** (dd/mm/yyyy) | **Result**<br>1=Normal<br>2=Abnormal, please specify<br>3= Not done |
|---|---|---|
| Chest x-ray | | |
| CT scan neck | | |
| CT scan chest | | |
| CT scan abdomen | | |
| CT scan pelvis | | |
| ECG | | |
| Specify abnormality | | |
| Echocardiogram | | |
| Specify abnormality | | |
| MUGA scan | | |
| Specify abnormality | | |
| CSF examination | | |
| Specify abnormality | | |
| Bone marrow aspirate | | |
| Specify abnormality | | |
| Bone marrow trephine | | |
| Specify abnormality | | |

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# Registration form (page 5 of 6)

**Sites of Nodal Disease**

| **Site** | **Involved**<br>Y=Involved<br>N= not involved | **Investigation**<br>1=clinical<br>2=x-ray<br>3=CT scan<br>4=other | **Measurable**<br>M=measurable<br>E=evaluable | **Size**<br>Bidimensional measurements (mm x mm) |
|---|---|---|---|---|
| Left cervical | | | | |
| Right cervical | | | | |
| Left supraclavicular | | | | |
| Right supraclavicular | | | | |
| Waldeyer's ring | | | | |
| Left axillary | | | | |
| Right axillary | | | | |
| Paratracheal | | | | |
| Mediastinal | | | | |
| Hilar | | | | |
| Retrocrural | | | | |
| Para-aortic | | | | |
| Coeliac axis | | | | |
| Mesenteric | | | | |
| Splenic | | | | |
| Portal | | | | |
| Left iliac | | | | |
| Right iliac | | | | |
| Left inguinal | | | | |
| Right inguinal | | | | |
| Left femoral | | | | |
| Right femoral | | | | |
| Other, specify | | | | |
| Other, specify | | | | |
| Other, specify | | | | |
| Other, specify | | | | |

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# Registration form (page 6 of 6)

**Sites of extranodal disease**

| **Site** | **Involved**<br>Y=Involved<br>N= not involved | **Investigation**<br>1=clinical<br>2=x-ray<br>3=CT scan<br>4=other | **Measurable**<br>M=measurable<br>E=evaluable | **Size**<br>Bidimensional measurements (mm x mm) |
|---|---|---|---|---|
| Spleen | | | | |
| Liver | | | | |
| Lungs | | | | |
| Bone marrow | | | | |
| Gastric | | | | |
| Kidney | | | | |
| Pericardium | | | | |
| Pleura | | | | |
| Skin | | | | |
| Testis | | | | |
| Other, specify | | | | |
| Other, specify | | | | |

Form completed by: _____ Date of completion: _____

Signature: _____

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|---|---|---|---|---|
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# Randomisation form (page 1 of 1)

**International Prognostic Index**

| **Criteria** | 1=Yes, 0=No |
|---|---|
| Age >60 years | |
| Tumour stage III or IV | |
| WHO performance status ≥2 | |
| Serum LDH greater than upper limit of local normal range | |
| More than one extranodal site | |
| **Total IPI score** | |

| **Eligibility confirmation** | Y=Yes, N=No |
|---|---|
| Does the patient fulfill all the eligibility criteria? | |
| Proof of written informed consent obtained | |

| **Eligibility confirmation** | |
|---|---|
| Is the patient taking part in the PET sub-study? (**Y=Yes, N=No)** | |
| If so, which PET centre will the patient be scanned at? | |
| Please give the date of the baseline scan **(dd/mm/yyyy)** | |

Form completed by: _____ Date of completion: _____

Signature: _____

| **For office use only**<br>**If sections above are completed and patient is eligible, proceed with randomisation** | |
|---|---|
| **Allocated trial number** | |
| **Arm A – R-CHOP21: CHOP for 8 cycles and rituximab for 8 cycles given every 21 days** | |
| **Arm B – R-CHOP14: CHOP for 6 cycles and rituximab for 8 cycles given every 14 days** | |
| **Randomised by** | **Date randomised (dd/mm/yyyy)** |